

REMARKS

Claims 1-45 remain in the application. Claims 1, 5, 14, 18, 22, 31, 37, and 42 have been amended herein to recite that one of the RNase inhibitor protein may be selected from "recombinant human placental sources." This recitation enjoys verbatim support in the application as filed at the bottom of page 7. As noted in great detail below, Applicants submit that this phrase is identical in scope to the phrase presented in Applicants' immediately prior response. Entry is necessary and was not submitted earlier because the Office objected to the earlier phrase. Applicants then amended in the claims in the manner suggested by the Office. The Office, however, then deemed the revised language to introduce new matter. Applicants have thus reverted the claim language back to its original format (which enjoys verbatim support in the specification as filed).

Claims 6 and 23 have been amended to be independent claims that incorporate the subject matter of their respective base claims and any intervening claims.

Claims 2, 3, 6, 11, 12, 19, 20, and 23 have been canceled. Such cancellation is without prejudice on the merits to further prosecution of these claims in one or more continuing applications.

Favorable reconsideration is respectfully requested.

Rejection of Claims 1-45 Under §112, First Paragraph (Written Description):

This rejection is respectfully traversed because the Office is applying an unduly high hurdle with respect to the requirements of §112, first paragraph, written description. In effect, the Office is rejecting Applicants's claims for failure to articulate a sufficient number of working examples. Applicants note that there is no requirement for the application to contain any working examples. On this point, see the Office's statement at the top of page 5 of the Office Action:

The specification also fails to describe additional representative species of RNase inhibitor proteins for use in the claimed methods by any identifying structural characteristics or properties necessary to ensure the successful use of these inhibitor proteins.

But, as noted in Applicants' immediately prior response, the specification as filed describes at least four (4) distinct types of proteinaceous RNase inhibitors, all of which will work in the present invention.

Having described a broad array of RNase inhibitor proteins, Applicants respectfully submit that the specification as filed contains sufficient written description to support the phrase "RNase inhibitor protein" as used in the current claims.

Also as noted earlier, defining a generic term (RNase inhibitor protein) by listing a number of exemplary species that fall within the generic term is an approved approach to defining a generic term. See MPEP §2164.08 and *In re Marzocchi*, 169 USPQ 367, 370 (CCPA 1971): "How a teaching is set forth, by specific example or broad terminology, is not important." (Emphasis added.)

Thus, in the present application, the specification clearly discloses human-derived RNase inhibitor proteins (both native and recombinant), rat-derived RNase inhibitor proteins, and porcine-derived RNase inhibitor proteins. All of these types of proteins, as well as others, are commercially available products. See Exhibits A, B, C, D, E, and F submitted with Applicants' prior response.

Regarding the revised guidelines concerning compliance with the written description requirement, these guidelines are promulgated at MPEP §2163. The guidelines provide far more leeway than the Office admits in the Final Office Action. In effect, the Examiner is requiring that the Applicants' establish structure-function relationship between the structure of a protein and its ability to act as an RNase inhibitor. MPEP §2163, however, is not so strict:

Possession may be shown in a variety of ways including... describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406; *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "**whatever characteristics sufficiently distinguish it**"). (Emphasis added.)

MPEP §2163 does not require that a "RNase inhibitor protein" be described by means of a structure-function relationship. On this point, Applicants note that they are not claiming the RNase inhibitor protein itself. Thus, many of the cases cited in MPEP §2163 (such as *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398, (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998), are inapplicable to the present claims. Applicants are not claiming a composition of matter or a compound, but rather a method. In short, Applicants respectfully submit that the Office is

applying a formulaic approach to the written description requirement, when the Guidelines clearly call for a more all-encompassing approach:

An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. See, e.g., *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483

Applicants therefore respectfully submit the specification provides a reasonable amount of information to convey to a person of ordinary skill in the art that Applicants were in possession of the invention at the time the application was filed.

Applicants therefore submit that the rejection of Claims 1-45 under §112, first paragraph, written description, is untenable. Withdrawal of the rejection is requested.

Rejection of Claims 5, 14, 22, 31, 37, and 42 Under §112, First Paragraph (New Matter):

This rejection is believed to have been overcome by appropriate amendment to the claims. Specifically, the claims have been amended to read, in relevant part "recombinant human placental sources," a phrase that Applicants submit is unambiguous and which appears verbatim in the specification as filed at page 7, second-to-last line.

If the Office takes a contrary position, Applicants' undersigned counsel respectfully requests the Examiner's assistance in addressing this rejection. In the Office Action dated July 27, 2006, the Office objected to Claim 5, stating (at the top of page 3 of the Office Action):

Claim 5 recites "recombinant human placental sources." This is interpreted as "recombinant sources of human placental" and it is suggested that this be amended to more accurately reflect such an interpretation.

Applicants didn't see then (and still fail to see now) how the Office's interpretation is any different than Applicants' intended meaning. So rather than argue the point back in 2006, Applicants amended the claims in accordance with the Examiner's suggestion. See Applicants' response filed November 27, 2006.

In the present Office Action at the top of page 6, the Office now rejects the claims under §112, first paragraph as adding new matter. The Office states that the relevant claims originally recited a

"recombinant human placental sources." The Office objected to this language in the earlier Office Action and specifically indicated that the term "recombinant source of human placental [proteins]" was more appropriate and explicitly invited Applicants to amend the claims "to more accurately reflect such an interpretation." The Office however now rejects the claims due to the latter term, stating that these two terms are "clearly" different in scope. But the Office does not articulate how or why "recombinant human placental sources" and "recombinant source of human placental [proteins]" are different in any sense. Applicants respectfully submit that the two terms are synonymous.

Because the rejection has been couched as a new matter rejection, Applicants have amended the claims herein to include the phrase "recombinant human placental sources." Again, this phrase appears verbatim at the bottom of page 7 of the application as filed.

Withdrawal of the rejection is respectfully requested. In the event the Office reiterates its earlier objection to the claims, Applicants' undersigned counsel further requests clarification from the Office as to why the phrase "recombinant human placental sources" is objectionable.

Rejection of Claims 1-45 Under §112, First Paragraph (Enablement):

As applied to Claims 5, 14, 22, 31, 37, and 42, Applicants submit that this rejection is untenable because these claims recite that the RNase inhibitor protein is derived from porcines, rats, human placentas, or recombinant sources of human placental proteins. Each of these sources of RNase inhibitor proteins is explicitly described in the specification as filed. These types of RNase inhibitor proteins are commercially available products. (See Exhibits A, B, C, D, E, and F of Applicants' prior response.) Because these products can be purchased commercially, the person of ordinary skill in the art can simply purchase the recited inhibitor proteins. Thus, as applied to Claims 5, 14, 22, 31, 37, and 42, Applicants respectfully submit that the rejection under the enablement clause of §112, first paragraph is clearly improper.

As applied to the remaining claims, this rejection is traversed.

The Office asserts, at page 9 of the Final Office Action, that the specification does not provide specific guidance on how to select a RNase inhibitor protein that can be used in the invention. Even if a

titanic amount of screening is required to determine if any given RNase inhibitor protein is suitable for use in the present invention, the screening is totally routine. There is no reason a person of ordinary skill in the art cannot practice the invention using any RNase inhibitor protein, now known or discovered in the future. A host of such proteins are now commercially available, as evidenced by the attached Exhibits. The person of ordinary skill in the art does not need to know anything at all about the protein, other than that it functions as an RNase inhibitor protein. That is all that the claims require. If the protein is an RNase inhibitor protein, it can be used in the claimed invention.

There is no requirement that Applicants, for example, articulate a "rational and predictable scheme for modifying any amino acid residue of any RNase inhibitor protein with an expectation of obtaining the desired biological function." Nor does a user of the presently claimed invention need to have any knowledge whatsoever of the "general tolerance of any RNase inhibitor protein to modification and the extent of such tolerance." See page 9 of the Office Action. Applicants are not claiming the inhibitor per se, nor are Applicants claiming a method of making the inhibitor, nor are Applicants claiming a method of modifying the inhibitor. Applicants again respectfully submit that the entire discussion at page 9 of the Final Office Action is irrelevant to the issue of enablement. The person of ordinary skill in the art can be completely, utterly and totally **ignorant of the structure of the RNase inhibitor protein** and still be fully capable of practicing the invention as broadly as it is claimed. For the commercially available RNase inhibitors, all the person of ordinary skill in the art needs to do is buy the inhibitor.

It is well-settled law that the Applicants **do not** have to have any knowledge whatsoever of **how** an invention functions. All Applicants have to do is show that the invention does work. Thus, the entire discussion contained in the Office Action regarding the structure of the RNase inhibitor protein and its tolerance to amino acid modification is irrelevant. Applicants are not claiming the RNase inhibitor protein itself. Applicants do not have to elucidate, nor do they have to claim, the underlying biological phenomenon by which the claimed invention operates. Again, the person of ordinary skill in the art can practice the invention without any knowledge whatsoever about the amino acid sequence of the RNase inhibitor protein. Insofar as a slew of RNase inhibitor proteins are staple articles of commerce, the

phrase "RNase inhibitor protein" is perfectly commensurate in scope with the disclosure contained in the application as filed.

In the present situation, a host of RNase inhibitor proteins are already known in the art and commercially available. Any of them will work. Some will work better than others. But there is no requirement in the patent law that all of the individual species falling within a generic term function with equal success. See, for example, *In re Gardner*, 177 USPQ 396 (CCPA 1973).

For the above reasons, Applicants respectfully submit that the rejection of Claims 1-45 under 35 U.S.C. §112, first paragraph, enablement is untenable. Applicants therefore respectfully request that this rejection now be withdrawn.

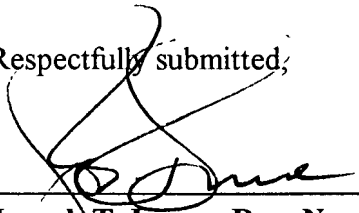
Rejection of Claims 1-5, 7-9, 18-22, and 24-25 Under §102(b) Over Ambion, Inc. "TechNotes" 8(2) (hereinafter "TechNotes"):

This rejection has been overcome by appropriate amendment to the claims. Specifically, the temperature recitation of Claim 6 has been incorporated into Claim 1 and the temperature recitation of Claim 23 has been incorporated into Claim 18. Claims 2, 3, 11, 12, 19, and 20 have been canceled.

Withdrawal of the rejection is respectfully requested.

Applicants submit that the application is now in condition for allowance. Early notification of such action is earnestly solicited.

Respectfully submitted,


Joseph T. Leone, Reg. No. 37,170
DEWITT ROSS & STEVENS S.C.
8000 Excelsior Drive, Suite 401
Madison, Wisconsin 53717-1914
Telephone: (608) 831-2100
Facsimile: (608) 831-2106

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